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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,012	09/14/2001	Colin Gerald Caro	BKY2-0074	7764

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

Office Action Summary	Application No. 09/857,012	Applicant(s) CARO ET AL	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 5, 6, 12-16, 24-31, and 42-43 is/are pending in the application.
 4a) Of the above claim(s) 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5, 6, 12-16, 24-31 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2005 has been entered.

Election/Restrictions

Newly submitted claim 43 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is directed to a method of use that was not originally presented and is patentably distinct from the product that can be used in materially different methods such as in the method of treating a the gastrointestinal tract or the bile duct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 43 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 42 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim language claims a combination of a stent with a naturally occurring article (i.e. an intact vessel). For this reason, the claim is considered non-statutory.

On April 7, 1987, then Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, set forth PTO policy on this issue in the form of a notice entitled "Animals – Patentability". The notice affirmed that the "Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101" and relied on the now famous Supreme Court decision *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). See MPEP 2105, last two paragraphs.

However, Commissioner Quigg's notice also went on to affirm the long-standing PTO principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101. Specifically, the Commissioner stated that a "claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101" since the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. The language "including within its scope a human being" is the important language here.

Accordingly, proper procedure where a claim is directed to apparatus "attached to" the human body or any part thereof is to reject such claim under 35 U.S.C. 101 with an explanation that, because the claim positively recites a part of the human body, it is directed to nonstatutory subject matter. Beyond the statute itself, proper authority for such a rejection is Commissioner Quigg's notice which was published at 1077 OG 24 (April 21, 1987).

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 6, 24-27, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by MacGregor (US 5,015,253) as evidenced by Prince (US 5,579,767). MacGregor anticipates the claim language where it is applied to and in the shape of an aneurysm and an aneurysm is known to produce swirl flow as evidenced by Prince; see Figure 2, column 1, lines 25-55 and column 6, lines 26-43 of MacGregor and see column 2, lines 26-36 of Prince. For this reason, the claim language is considered fully inherently met. The shape and/or orientation of the stent is considered non-planar because it is a cylinder. Cylinders are considered to be non-planar curves, to the extent this language can be given patentable weight, because a cylinder is a curved three-dimensional shape where no area of its surface is in the same plane.

Regarding claim 26, Applicants are directed to column 2, lines 21-31, column 4, lines 6-19, and column 6, lines 26-43 where the expanded shape is retained or remembered to the extent that the language "shape memory alloy" can be given patentable weight.

Claims 42 is rejected under 35 U.S.C. 102(b) as anticipated by Caro (WO 95/09585). Caro anticipates the claim language where the stent with supporting part as claimed is met by the shaped vascular prosthesis that includes "a stent or other

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structural support of plastic, metal or other material"; see the abstract and page 5, line 28 to page 6, line 10. This shaped tube of Caro especially with a metal stent therein would inherently impose a shape on a vessel it is inserted into because it is designed to be rigid enough to prevent kinking or collapse. The tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30. The stent of Caro can be outside the tube such that it "internally supports" the blood vessel it is inserted into.

Claims 3, 5, 6, 24-30 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 95/09585) in view of Fischell et al (US 5,697,971). Caro meets the claim language as set forth above but fails to disclose the type of stent, one that has wall openings, as claimed. Specifically, the supporting portion as claimed is met by the external stent of Caro and the entire externally supported prosthesis can be inserted into the vessel; see the previously cited portions. Fischell teaches that the claimed stent, one with wall openings, was known to the art; see Figure 2 and Column 2, line 37 to Column 3, line 22. Therefore, it is the Examiner's position that it would have been obvious to use the Fischell stent as the stent of Caro because it would provide a means to prevent collapse and kinking, as is the desire of Caro. When the externally supported or stent prosthesis of Caro as modified by Fischell is inserted into the blood vessel, the openings of the stent would be open to the extent required, only covered by the tubing (1) of Caro.

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Regarding claim 26, the stainless steel of Fischell is an alloy of iron and chromium. It has shape memory in that it retains the shape it is expanded to; see column 2, lines 36-46.

Regarding claims 28-30, the links as claimed are met by elements (16) of Fischell.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 3, 5, 6, 24-30 and 42 above, and further in view of Wolff (US 5,104,404). Caro as modified by Fischell has a stent with wave-shaped links but lacks the coil structure as claimed. However, Wolff teaches that it was known to make links with coil shapes; see Figure 3. Therefore, it would have been obvious to form the links of Caro as modified by Fischell into a coil form for the same reason as Wolff and since such coils would result in a great deal of flexibility between the "rings."

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 3, 5, 6, 24-30 and 42 above, and further in view of Schwartz et al (6,015,387). Caro fails to disclose the monitoring device as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor, which must have a power supply and recording means to function. This is necessary

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because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*.

Response to Arguments

In response to the assertion that the amendment to claim 42 renders is statutory under Section 101, the Examiner does not agree. In particular, the claim still calls for a combination of the stent with a naturally occurring material (an intact vessel). The Examiner suggests amending claim 42 to have language similar to that of claim 24 in order to overcome this rejection.

In response to the argument that the vessel part would be fully shielded by the device of Caro, the Examiner disagrees and asserts that the claim language of claim 24 only requires that the support portion have a hollow tube with holes in it. Since the stent of Caro as modified by Fischell is the support portion of the device and since the Fischell stent has openings in it, the Examiner asserts that the claim language is fully met. It is noted that claim 42 was not amended to set forth openings, and thus, the rejection under Section 102 has been maintained.

On page 8 of the January 28, 2005 response, Applicants argue that Caro does not disclose a stent in place within an intact vessel. However, the Examiner asserts that only the structure of the device is required for anticipation not the intended use of the device. Furthermore, Caro is interpreted as disclosing that the prosthesis is inserted within a blood vessel; see page 6, lines 24-30.

In response to the argument that Caro is not capable of imposing a shape on a vessel, the Examiner asserts that the properties of the vessel have not been set forth

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such that the "vessel" fails to imply or infer any structure on the stent. Additionally, the tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30.

Conclusion


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Paul Prebilic
Primary Examiner
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